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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
AGRAWAL, RITESH	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/506,409	CHILINGARIAN ET AL.	
	Examiner	Art Unit	
	Ritesh Agrawal	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 01 September 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendments

1. Applicant's preliminary amendment, dated 02/15/06, has been entered.

Specification

2. The disclosure is objected to because of the following:

The use of the trademarks LIFEARRAY and GENECHIP have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. They can be found, for example, on page 6 of the specification.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;

(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it is not placed on a separate sheet. In addition, while the claims are drawn to methods, no method steps are provided. Furthermore, the abstract refers to speculative applications of the invention. Correction is required. See MPEP § 608.01(b).

Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The following analysis of facts of this particular patent application follows the analysis suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility"[1]. Note that the text of the Guidelines is italicized.

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.

- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

In the instant case, the claimed invention does not "transform" an article or physical object to a different state or thing because it merely analyzes gene expression data to identify a set of differentially regulated genes. This does not preclude the subject matter to be patentable as, for eligibility analysis, as

physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452. If the examiner determines that the claim does not entail the transformation of an article, then the examiner shall review the claim to determine if the claim provides a practical application that produces a useful, tangible and concrete result. In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete." The claim must be examined to see if it includes anything more than a § 101 judicial exception. If the claim is directed to a practical application of the § 101 judicial exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a practical application, the examiner has determined that the claim is nonstatutory. (Guidelines, p. 20)

[1] Available at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

The question is thus whether the final result achieved by the claimed invention satisfies all three criteria of being useful, and concrete, and tangible.

Furthermore, the useful, tangible, and concrete result must be recited in the claim itself, rather than addressed in specification.

(2) **"TANGIBLE RESULT"** The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. The opposite meaning of "tangible" is "abstract."

The instant claims are drawn to computational means for analysis of gene expression data. However, as claimed, the method does not produce a tangible result. For example, the method as claimed may take place entirely within the confines of a computer or a human mind without any communication to the outside world and without using or making available for use, the results of the computation. Thus, the instant methods of the claims do not produce any tangible result.

Thus, the final result achieved by the claimed invention does not satisfy all three criteria of being useful, and concrete, and tangible.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, and 5 recite the limitation "the distinctiveness" in line 11. There is insufficient antecedent basis for this limitation in the claim. There is no prior reference to the term "distinctiveness."

Claims 1, 3, and 5 recite the limitation "the values of the quality function" in line 15. There is insufficient antecedent basis for this limitation in the claim. There is no prior reference to "values of the quality function."

Claims 1, 3, and 5 recite the limitation "the locally optimal subsets" in lines 24-25. There is insufficient antecedent basis for this limitation in the claim. There is no prior reference to locally optimal subsets only "a locally optimal subset."

Claims 1, 3, and 5 recite the limitation "said set of genes" in line 27. There is insufficient antecedent basis for this limitation in the claim. There is no prior method step that recites a "set of genes."

The term "larger" in claims 1, 3, and 5 is a relative term which renders the claim indefinite. The term "larger" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to what the term "larger" refers. Does it refer to the number of genes or the size (number of basepairs within) of the genes.

Claim 8 recites the limitation "the final subsets" in line 3. There is insufficient antecedent basis for this limitation in the claim. There is no prior reference to "final subsets."

The term "sufficiently" in claim 10 is a relative term which renders the claim indefinite. The term "sufficiently" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is thus unclear as to how small the first predetermined number needs to be to meet the claim limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Chilingaryan et al. (Mathematical Biosciences, Vol. 176, Pages 59-69, Published Online December 28th, 2001).

The claims are drawn to a method for identifying a set of genes from two states comprising:

(a) identifying a quality function to evaluate the difference between a first and second plurality of microarray data

(b) selecting a subset of genes from all of the genes studied

(c) calculating values by applying the quality function to the subset of genes

(d) substituting a gene in the selected subset with one outside the selected subset, repeating step (c), keeping the subset with the substituted gene if the difference between the pluralities increases and keeping the original subset otherwise

(e) repeating steps (c) and (d) a predetermined number of times

(f) repeating steps (b) to (e) a second predetermined number of times

(g) integrating the subsets obtained in (f) with all of the genes

Chilingaryan et al. disclose the method steps (see steps 1-5 on page 61) and apply it to the states of aggressive and less aggressive colon cancers (page 66, 2nd paragraph, lines 1-4).

With respect to claim 2, Chilingaryan et al. disclosure of different states of colon cancer (as cited above) represents different biological and pathological states.

With respect to claim 3, Chilingaryan et al. disclosure of different cancer samples (as cited above) represents the use of different tissues.

With respect to claim 4, Chilingaryan et al. disclose abnormal colon tissues in their disclosure of colon cancer tissues (as cited above).

With respect to claim 5, Chilingaryan et al. disclose application of their method to the HT29 and HCT116 cell lines (page 66, 2nd paragraph, lines 1-4).

With respect to claim 6, Chilingaryan et al. disclose abnormal colon cells (as cited above).

With respect to claim 7, Chilingaryan et al. disclose using cultured cells (page 66, 2nd paragraph, lines 4-5).

With respect to claims 8 and 9, Chilingaryan et al. disclose using 1% as a frequency cutoff for the inclusion of genes (page 68, 2nd paragraph, line 1).

With respect to claim 10, Chilingaryan et al. using a first predetermined number such that a global maximum is not reached (page 64, 7th paragraph, line 3).

With respect to claim 11, Chilingaryan et al. disclose the quality function can be parametric or non-parametric (page 61, 4th paragraph, line 6).

With respect to claim 12, Chilingaryan et al. disclose that the parametric function can be either a Mahalanobis distance (page 62, 5th paragraph, line 9) or Bhattacharya distance (page 63, 1st paragraph, line 1).

With respect to claim 13, Chilingaryan et al. disclose using spotted arrays (page 60, 2nd paragraph, line 1).

6. Claims 1-8 and 10-11, and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Li et al. (Bioinformatics, Vol. 17, Pages 1131-1142, December, 2001) and Li et al. (Combinatorial Chemistry and High Throughput Screening, Vol. 4, Pages 727-739, December 2001).

The inclusion of the second reference is to further define the algorithm used by Li et al. in the Bioinformatics reference.

The claims are drawn to a method for identifying a set of genes from two states comprising:

(a) identifying a quality function to evaluate the difference between a first and second plurality of microarray data

(b) selecting a subset of genes from all of the genes studied

(c) calculating values by applying the quality function to the subset of genes

(d) substituting a gene in the selected subset with one outside the selected subset, repeating step (c), keeping the subset with the substituted gene if the difference between the pluralities increases and keeping the original subset otherwise

(e) repeating steps (c) and (d) a predetermined number of times

(f) repeating steps (b) to (e) a second predetermined number of times

(g) integrating the subsets obtained in (f) with all of the genes

Li et al. disclose a method for identifying a set of genes from two states (abstract, lines 3-4 and page 1132, 1st column 3rd paragraph, line 4, and page 1132, 1st column, 4th paragraph, lines 2-3).

Li disclose using a k-nearest neighbor function combined with a genetic algorithm to discriminate between classes of samples (page 1131, 2nd column, 2nd paragraph, lines 2-7).

They select subsets of genes into arrangements they call chromosomes (page 1133, 1st column, 4th paragraph, lines 1-5).

The chromosomes are allowed to exchange genes and chromosomes are kept or lost based upon the distinctiveness obtained through mutation or gene maintenance (see Combinatorial Chemistry reference, page 730, 2nd column, 2nd paragraph, and figure 1) where the replacement occurs for a predetermined number of times (2nd column, 2nd paragraph, line 3).

Steps (b) through (e) are repeated 10,000 times (Bioinformatics reference, page 1134, 2nd paragraph, lines 1-2).

Li et al. then integrate the results of these various iterations with all of the genes to select those genes occurring a certain frequency of times (see, for example, Bioinformatics, figure 1, "sort all genes").

With respect to claim 2, Li et al. disclose using cancer versus normal or different cancer states (page 1132, 1st column 3rd paragraph, line 4, and page 1132, 1st column, 4th paragraph, lines 2-3) thereby disclosing different biological, physiological and pathological states.

With respect to claim 3, Li et al. disclose using different samples (as cited above) and are therefore using different tissue.

With respect to claim 4, Li et al. disclose tissues including cancer lung tissues (as cited above), and normal and abnormal colon tissues (as cited above).

With respect to claim 5, Li et al. disclose using different samples with different cancer or non-cancer properties (as cited above) and therefore disclose working with different cells.

With respect to claim 6, Li et al. disclose using cancer lung cells (as cited above) as well as normal and abnormal colon cells (as cited above).

With respect to claim 7, the cells of Li et al. were isolated from an organism (See, supplemental reference, Alon et al., PNAS, Vol. 96, Pages 6745-6750, 1999, page 6745, 2nd column, 2nd paragraph).

With respect to claim 8, Li et al. disclose using the 50 most frequently selected genes (page 1138, 1st column, 2nd paragraph, lines 1-4).

With respect to claim 10, Li et al. disclose that the chromosomes (subsets) they obtain are near-optimal and therefore should not represent the actual global maximum (for example, Bioinformatics, fig. 1, "Near-optimal solutions").

With respect to claim 11, Li et al. disclose the use of a non-parametric method (page 1131, 2nd column, 2nd paragraph, line 5).

With respect to claim 13, the data used by Li et al. is generated from oligonucleotide arrays (see Alon et al. reference, abstract) and cDNA arrays (see Supplemental reference, Alizadeh et al., Nature, Vol. 403, Pages 503-511, 2000, especially page 504, "Construction of Specialized Microarray").

Conclusion

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal

SHUBO (JOE) ZHOU, PH.D.
PATENT EXAMINER